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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/798,060

Filing Date: March 10, 2004

Appellant(s): BOBROFF ET AL.

John F. Perullo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 16, 2009 appealing from the Office action mailed January 8, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,153,828	INOUE ET AL	10-1992
5,876,387	KILLIAN ET AL	03-1999
5,989,234	VALERIO ET AL	11-1999
5,116,312	BLANKENSHIP ET AL	5-1992

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,153,828).

With respect to **claims 1-5 and 7-9**: Inoue et al. disclose a fluid monitoring and alert system 10 comprising a fluid collection device—having a drain tube 2, a vacuum reservoir 13, a suction pathway 41/others—vacuum pump (compressor) 17, sensors 40, 71, 73, a controller 18, an audible alarm 69, a visual display 12, and a valve 43 (whole document). The system records

and displays data related to the system, including pressure data, via memory 66. The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68).

With respect to **claim 11**: It has been held that a recitation with respect to the manner in which a claimed invention is intended to be employed does not differentiate the claimed invention from a prior art satisfying the claimed structural limitations. *Ex parte Maham*, 2 USPQ2d 1647 (1987).

In re Paulsen, 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994). Therefore, the system is considered capable of being used in the manner claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al ('828).

With respect to **claim 12**: Inoue discloses that data, such as the amount of blood collected, is to be displayed on the visual display but does not expressly disclose the intervals at which this data is to be sampled or displayed. However, the interval at which the data is sampled affects the accuracy of the information displayed to the user. As such, the interval at which data is collected and/or displayed to the user is considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to have the display show data such as the volume of liquid collected in intervals of fifteen minutes, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to **claim 14**: Inoue does not teach that historical procedural data from a plurality of previous time intervals are displayed on the visual display along with the current procedure data. However since Inoue teaches memory 66 that stores data received from the at least one sensor and a visual display, it would be obvious to one of ordinary skill in the art to modify the device of Inoue such that the memory 66 and display 12 are operatively associated such that historical procedure data from a plurality of previous time intervals are displayed on the visual display along with the current procedure data with a reasonable expectation of success to provide additional information to the caregiver. (Col. 7, lines 6-10)

With respect to **claim 15**: Inoue discloses a fluid monitoring and alert system 10 comprising a fluid collection device having a vacuum reservoir 13 configured to be placed in communication

with a suction pathway 41 that is at least partially defined by a surgical drain tube 2. At least one liquid collection sensor 40, 71, 73 configured to obtain data from the suction pathway. Controller 18 is connected to the at least one sensor 40, 71, 73 and inherently and necessarily has instructions to receive current procedure data from the sensor. The system records (saves) and displays data related to the system, including pressure data, via memory 66. Thus since the system stores and saves data, the system inherently and necessarily saves the data already received to create historical procedure data. The system has an audible alarm 69 that is activated when blood leakage is detected, an event that constitutes a predefined trend in the data of unexpected decrease in expected predefined blood volumes at certain time intervals. The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68). Inoue does not teach that the controller compares the current procedure data to the historical procedure data stored in memory 66. However, since Inoue teaches memory 66 that stores data received from the at least one sensor, it would be obvious to one of ordinary skill in the art to modify the device of Inoue such that the controller can compare the current procedure data received with the historical procedure data already stored in memory 66 with a reasonable expectation of success to provide additional information to the caregiver via display 12. (Col. 7, lines 6-10)

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Killian et al. (US 5,876,387).

With respect to **claim 6**: Inoue discloses the claimed invention but does not expressly disclose that the vacuum reservoir is joined to a facility-wide source of suction. Killian teaches a suction system to be used in a medical facility comprising a vacuum chamber and pump. Killian teaches

that the system is connected to a central suction facility in case of failure of the vacuum pump (column 1, lines 39-64). One would have been motivated to modify the system of Inoue et al. to have the vacuum reservoir connected to a central suction facility, as taught by Killian, since doing so would allow for a replacement source of suction in the event of failure of the vacuum pump. Thus, it would have been obvious to one of ordinary skill in the art to modify the device of Inoue so as to have the vacuum reservoir connected to a facility-wide source of suction, as taught by Killian, since doing so would allow for a replacement source of suction in the event of failure of the vacuum pump.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Valerio et al. (US 5,989,234).

With respect to **claim 10**: Inoue discloses the claimed invention but does not expressly disclose that the system comprises an autotransfusion device. Valerio discloses a system for draining and collecting fluid from a body cavity comprising a vacuum pump and chamber. Valerio discloses that the device can be modified to serve as an autotransfusion device since reinfusing the patient's own blood is advantageous given today's concerns with communicable diseases (column 17, lines 22-29). (Also see Blankenship et al. US 5,116,312, column 1, lines 28-43). Thus, it would have been obvious to one of ordinary skill in the art to modify the system of Inoue to comprise an autotransfusion device, as taught by Valerio, since doing so would provide the additional advantages of transfusing a patient with their own blood, or other bodily fluid.

(10) Response to Argument

Applicant's arguments filed March 16, 2009 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection of claims 1-5 and 7-9 under 35 U.S.C. 102: Applicant argues that the Inoue system does not disclose a controller configured to compare current procedure data to historical procedure data and activate an alarm when trends are detected. First, any controller, including that disclosed by Inoue, that contains a CPU with memory is configured to compare current data with past or historical data because the memory can store the data and compare because a CPU is fully capable of executing algorithms to compare collected and/or stored data. This is supported by Inoue's disclosure in Col. 8, lines 24-40, where Inoue discloses calculation of blood yet-to-be-collected from previously registered weight of the blood bag (i.e. historical procedure data) and set blood collection amount. This necessarily requires comparison of the yet-to-be-collected amount of blood, with the set collection amount, which examiner also considers to be historical procedure data as it was entered at the start of the procedure before the current data is collected. Whether the data is obtained by equipment elements or calculated from an algorithm is immaterial, as both are examples of procedure data, current or historical. Second with regard to the limitation configured to activate an alarm when predefined trends in the data are detected, these trends are neither explicitly recited in the claims nor defined in the specification. Applicant only refers to trends which indicate a problem with the patient's physiological condition or the performance of the system. Inoue discloses four conditions which cause a buzzer 69, i.e. an alarm, to be activated, one of which is a detection of blood leakage, which examiner considers herein to be a predefined trend as that term is understood from applicant's disclosure. ('828, Col. 6, lines 62-68, Col. 7, lines 20-27)

As to applicant's argument that there can be no misunderstanding of what is meant by "current procedure data" and "historical procedure data", merely reciting these terms in the claims does not define them. There are no further limitations with regard to the data and applicant's specification does not even refer to the data using those exact words, providing a clear definition. The specification refers to current and historical performance data, not procedure data. Thus, as stated *supra* in this section of this Office action, the current and historical data disclosed by Inoue and collected or yielded by calculation meet the limitations of current procedure data and historical procedure data.

With respect to arguments regarding the rejection of claims 6, 10, 12, 14 and 15 under 35 U.S.C. 103: Applicant argues with regard to claim 12 that changing the interval at which data is collected would not impact accuracy and thus is not a result-effective variable that can be optimized. First, the final action also uses the word "reliability" to more clearly state what examiner refers to when using the word "accuracy". As was also stated in the final action, collected data at smaller intervals allows for a better portrayal of trends than larger intervals, as some trends in the patient's condition may change only temporarily but still need to be attended to and the trend of change may not be detected when the time interval between data collection instances is larger. Second, the fifteen minute time interval has no criticality associated with it in the disclosure and in fact is only disclosed as an example. Thus, examiner maintains the position that the fifteen minute time interval recited in claim 12 is merely an optimizable parameter of the claimed system and thus unpatentable over Inoue.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Melanie J Hand/

Examiner, Art Unit 3761

Conferees:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

/Leslie R. Deak/

Primary Examiner, Art Unit 3761